DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 19, 2014

Genadyne Biotechnologies Incorporated
Mr. Chien-Ming Goh
Vice Presdient
16 Midland Avenue
Hicksville, New York 11801

Re: K141437
Trade/Device Name: Genadyne XLR8 Plus (XLR8+) Wound Vacuum System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 19, 2014
Received: August 21, 2014

Dear Mr. Goh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K141437

Device Name: Genadyne XLR8 Plus (XLR8+) Wound Vacuum System

Indications For Use:

The XLR8 Plus (XLR8+) Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

Prescription Use ___X__		**Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D)	**OR**	**(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Special 510k Summary

General Information **Date: May 28, 2014**

1.	**Applicant**	Genadyne Biotechnologies, Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.487.8787 (f) 516.977-8974
2.	**Contact Person**	Mr. Chien-Ming GOH (Andrew) Vice President Genadyne Biotechnologies Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.217.0101 (f) 516.977.8974
3.	**Trade Name**	XLR8 Plus (XLR8+) Wound Vacuum System (Ref: A4-S0003)
4.	**Common Name**	Powered Suction Pump
5.	**Classification Name**	Negative Pressure Wound Therapy Powered Suction Pump
6.	**Regulation Number**	21 CFR 878.4780
7.	**Product Code**	OMP
8.	**Class in which Device has been placed**	Class II
9.	**Panel**	General & Plastic Surgery
10.	**Reason for Premarket Notification**	New Device
11.	**Identification of Legally Marketed Device Which We Can Claim Substantial Equivalence (Predicate Device)**	A4-XLR8 Wound Vacuum System K090638
12.	**Brief Description of Device**	The XLR8 Plus (XLR8+) Wound Vacuum System is portable, rechargeable battery powered wound suction pump with the intention to deliver negative pressure to the wound. The XLR8 Plus (XLR8 +) is a modification to the existing A4-XLR8 wound vacuum system with exactly the same internal components and accessories.

13.	**Indications for use [21 CFR 807.92(a)(5)]**	The XLR8 Plus (XLR8 +) Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

14**. Technological Characteristics**

Everything in the XLR8 Plus (XLR8+) Wound Vacuum System is exactly the same as the predicate device, the A4-XLR8 Wound Vacuum System, with the exception of an increment in depth of 1” to the back cover housing. The XLR8+ is a lightweight, portable wound suction device. It has a rechargeable battery, LCD screen for clear viewing, membrane overlay with buttons to control the device. It has 2 therapy options, continuous therapy and variable intermittent therapy. It consists of 5 alerts to notify the users of unwanted events, i.e. leakage in the dressing, blockage in the tubing, canister is full, low battery and critical battery status.

Table of Comparison to Predicate Devices:

Comparative Information		
	Predicate Device	**New Device**
Company	Genadyne Biotechnologies	Genadyne Biotechnologies
Device Name	A4-XLR8 Wound Vacuum System	XLR8 Plus (XLR8+) Wound Vacuum System
510 (K) Number	K090638	
Technical Data		
Suction Capacity	3.5 liters per minute	3.5 liters per minute
Max Vacuum	230 mmHg	230 mmHg
Power Requirements	30W	30W
Battery Type	Rechargeable Li-Ion	Rechargeable Li-Ion
Dimensions / Weight	5.9" x 4" x 2.4" / 1.5 lbs	5.9" x 4" x 3.4" / 1.65 lbs
Accessories		
Canisters	200, 400, 600, 800 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection	200, 400, 600, 800 ml disposable canister with a build-in hydrophobic shut off filter for overflow protection
Reusable	No	No
Sterile	Non Sterile	Non Sterile
Accessory Kit		
	A4-XLR8 Foam Dressing (K092992)	A4-XLR8 Foam Dressing (K092992)
Indications for Use		
	Genadyne A4-XLR8 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.	Genadyne XLR8 Plus Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.
Contraindications		
	The Genadyne A4-XLR8 is	The Genadyne XLR8 Plus is

	contraindicated in the presence of :	contraindicated in the presence of:
-	Necrotic tissue	Necrotic tissue
-	Untreated osteomyelitis	Untreated osteomyelitis
-	Malignancy (with exception to enhance quality of life)	Malignancy (with exception to enhance quality of life)
-	Untreated malnutrition	Untreated malnutrition
-	Exposed arteries, veins, or organs	Exposed arteries, veins, or organs
Precautions		
	Precautions should be taken for patients who are or may be:	Precautions should be taken for patients who are or may be:
-	Receiving anticoagulant therapy	Receiving anticoagulant therapy
-	Suffering from difficult hemostasis	Suffering from difficult hemostasis
-	Untreated for malnutrition	Untreated for malnutrition
-	Non-complaint or combative	Non-complaint or combative
Compliance		
	IEC 60601-1, 3rd Edition	IEC 60601-1, 3rd Edtion
Storage / Transport		
	-18°C to +43°C (0°F to 110°F)	-18°C to +43°C (0°F to 110°F)
	Relative Humidity 10% to 95 %	Relative Humidity 10% to 95 %
	700 - 1060 mbar Atmospheric pressure	700 – 1060 mbar Atmospheric pressure
Operation	18°C to 34°C (65°F to 94°F)	18°C to 34°C (65°F to 94°F)
	Relative Humidity 10% to 95 %	Relative Humidity 10% to 95 %
	700 - 1060 mbar Atmospheric pressure	700 - 1060 mbar Atmospheric pressure
Additional Testing		
	IEC 60601-1-2	IEC 60601-1-2

15. **Conclusion & Determination of Substantial Equivalence**

Based on the information presented above, it is concluded that the XLR8 Plus (XLR8+) is substantially equivalent to the predicate device.